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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DEBERRY, REGINA M

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 09/17/2003

42

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/029,042

Examiner

Regina M. DeBerry

Applicant(s)

KIM ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,7,10,11,15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7,10,11,15 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 16 June 2003 (Paper No. 41) has been entered in full. Claims 2, 3, 6, 8, 9, 12-14, 16 and 18-21 were cancelled. Claims 1, 4, 5, 7, 10, 11, 15 and 17 are under examination.

The instant applicant fully complies with sequence rules 37 CFR 1.821-1.825.

The species election requirement for EPO polynucleotides sequences (01 June 2001, Paper No. 24) is withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejection of claims 1, 4, 7, 10, 15 under 35 USC 102(e) as set forth at pages 4-5 of the previous Office Action (03 February 2003, Paper No. 40) is *withdrawn* in view of the amendment (16 June 2003, Paper No. 41).

The rejection of claims 15 and 17 under 35 USC 112, second paragraph as set forth at page 8 of the previous Office Action (03 February 2003, Paper No. 40) is *withdrawn* in view of the amendment (16 June 2003, Paper No. 41).

The objection of claims 5 and 11 as set forth at page 8 of the previous Office Action (03 February 2003, Paper No. 40) is *withdrawn* in view of the amendment (16 June 2003, Paper No. 41).

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Claim Rejections - 35 USC § 112, First Paragraph

Claims 1, 4, 5, 7, 10, 11, 15 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1, 7, 15 and 17 are drawn to a QT-VC cell. The invention appears to employ novel avian cells. The basis for this rejection is set forth at pages 6-7 of the previous Office Action (03 February 2003, Paper No. 40). Applicants contend that cell line QT-VC is readily available to the public since it can be obtained from QT35-N4D4 deposited as accession number of KCTC 0277BP in international authority, Korean Research Institute of Bioscience and Biotechnology Korean Collection for Type Cultures under the Budapest Treaty. Applicants submit a copy of the receipt of the original deposit.

Applicants' arguments have been fully considered but not deemed persuasive. The specification states that **QT-VC**, which was isolated by the inventors, was deposited to the International Depository Authority, Korea Research Institute of Bioscience and Biotechnology Korean Collection for Type Culture and assigned a deposit number of **KCTC 0277BP** on August 22, 1996. However, in the receipt of the original deposit that Applicants have submitted, the identification reference recites **QT35-N4D4** with number **KCTC 0277BP**.

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The specification teaches that deposited QT-VC was transfected with expression vector containing SY-EPO cDNA as described in Figure 8 (page 3, lines 7-12). The specification describes the construction of QT-VC cells stably expressing EPO. One of the subclones obtained through this procedure is **QT-N4D4** (page 22, line 28-page 23, line 1). **QT-VC** is a quail fibrosarcoma established cell line isolated by the inventors and **QT-N4D4** is the quail fibrosarcoma cell line which is stably expressing EPO. Thus, the Examiner has determined that there has to be two deposits for the novel established cell lines (QT-VC and QT-N4D4). The deposit submitted by Applicant appears to be for QT-N4D4. Applicant is incorrect in stating that QT-VC can be obtained from QT-N4D4 because they are two different established cell lines. If the deposit is made under the Budapest Treaty, a statement by an attorney of record over his or her signature and registration number stating that the nucleic acid molecules will be irrevocably and without restriction or condition released to the public upon the issuance of a patent is needed.

Lastly, the instant claims are drawn to QT-VC. The claims are not enabled for *any* QT-VC line, only those deposited with an accession number.

Claims 1, 4, 5, 7, 10, 11 and 17 are not enabled. Claims 4 and 10 are drawn to EPO genomic DNA. Claims 1, 7 and 17 are drawn to EPO. Claims 5 and 11 are drawn to SH (SEQ ID NO:5). The specification states that genomic structure of EPO cloned by the above method is different from the natural EPO genome *in vivo*. That is, wild type EPO genomic DNA has five coding regions and four introns between them. However, in

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the DNA cloned by the above method, the first coding region was fused to the second region to form one coding region so that it has four coding regions and three introns.

The specification states that the results from the analysis of EPO gene sequences isolated from four people suggested that nucleotide sequences of EPO cloned from these regions are significantly different from those of the prior two EPOs (AM-EPO and GI-EPO) (Figures 4, 5 and page 15, line 24-page 16, line 6). Amino acid sequences from AM, GI and SY are identical. Amino acid sequences from three people (JM, SH and HE) differ by two or three different amino acids from GI and AM EPO, suggesting that there is a polymorphism among people (page 16, lines 14-18). The specification teaches that SY-EPO cDNA was cloned generating the EPO expression vector, pIGA-EPO (page 6, lines 18-20 and Figure 8). The specification teaches the construction of QT-VC stably expressing SY-EPO cDNA (page 22, line 10-page 23, line 9).

The subject matter sought to be patented as defined by the claims is not supported by an enabling disclosure. Applicants have only taught the construction of SY-EPO in a vector comprising HCMV MIEP promotor and the stable expression of that particular vector in QT-VC cells. It cannot be assumed that the QT-VC cell line will stably express and efficiently produce the other forms of EPO (genomic EPO, EPO, SH) or give comparable biological activity as SY-EPO. The claims are also drawn broadly to EPO, which encompasses all forms and species. Lastly, SY-EPO is not EPO genomic DNA, it has been modified as was taught in the specification (four coding regions and three introns).

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Due to the large quantity of experimentation necessary to generate the infinite number of derivatives of EPO as encompassed in the claims, clone those EPOs into vectors, stably transfect those expression vectors into QT-VC cell lines, screen for established cell lines and then screen for activity of those expressed EPO proteins, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to same, the complex nature of the invention, the unpredictability of transfection and production efficiency and biological activity for other forms of EPO, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



RMD

September 11, 2003



ELIZABETH KEMMERER
PRIMARY EXAMINER